K081210

NIPRO MEDICAL CORPORATION
3150 N.W. 107 Avenue
Miami, Florida 33172
Tel.: (305) 599-7174
Fax: (305) 599-8454

OCT 21 2008

510(k) Summary
NIPRO SafeTouch Huber Infusion Set

807.92(a) (1)

Applicant: Nipro Medical Corporation
Establishment Reg.: 1056186

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: April 16, 2008

807.92(a) (2)

Trade Name: NIPRO SafeTouch Huber Infusion Set
Common Name: Huber Infusion Set
Classification Name: (21 CFR 880.5440)
Product Code: 80 FPA

807.92(a) (3)

Legally marketed substantial equivalent device:
EXEL SecureTouch Safety Huber Infusion Set

807.92(a) (4)

Description of device:
The Nipro SafeTouch Huber Infusion Set is a standard non-coring Huber type needle and administration set with an integrated safety mechanism to prevent in accidental needlesticks. This device is designed for use with a vascular access infusion system and is intended for use as an intravascular administration set to access surgically implanted subcutaneous vascular ports in a standard manner for the purposes of fluid or drug infusion and blood sampling.

807.92(a) (5)

Indications for Use:
This product is a safety intravascular administration set and is indicated for the administration of fluids and drugs, or blood sampling through surgically implanted vascular ports. Secondly, it incorporates a safety mechanism to help protect against exposure to blood borne pathogens caused by accidental needlestick injuries.

807.92(a) (6)

Comparison of technological characteristics:

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The NIPRO SafeTouch Huber Infusion Set is substantially equivalent to the predicate device in the following technological characteristics –

- Design
- Physical characteristics
- Basic Scientific Technology
- Intended Use

807.92(b) (1)

Non-clinical tests performed and included in this submission include:

- Dimensional
- Mechanical
- Performance
- Biocompatibility

807.92(b) (3)

Conclusions drawn from non-clinical and clinical tests:
The results of the non-clinical tests and the comparison of technological characteristics with the predicate device demonstrate that the NIPRO SafeTouch Huber Infusion Set performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2008

Ms. Jessical Oswald
Regulatory Affairs Specialist
Nipro Medial Corporation
3150 North West 107th Avenue
Miami, Florida 33172

Re: K081210
Trade/Device Name: NIPRO SafeTouch Huber Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 2, 2008
Received: October 3 2008

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

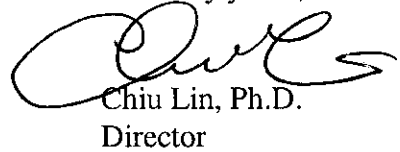
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: NIPRO SafeTouch Huber Infusion Set

Indications for Use:

This product is a safety intravascular administration set and is indicated for the administration of fluids and drugs, or blood sampling through surgically implanted vascular ports. Secondly it incorporates a safety mechanism to help protect against exposure to blood borne pathogens caused by accidental needlestick injuries.

ivision Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K081210

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)